

Notice of Allowability

Application No.

10/643,804

Examiner

Matthew J. Kremer

Applicant(s)

FREGER ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.
2. ☒ The allowed claim(s) is/are 1-19.
3. ☒ The drawings filed on 19 August 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>8/19/03; 8/13/04</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Bruce E. Lilling (Reg. No. 27,656) on 5/23/2005.

The application has been amended as follows:

In claim 3, line 3, "ultra sound" was changed to --ultrasound--.

In claim 8, line 7, --calculation-- was inserted after "analyte".

Claim 9 was rewritten as follows:

9. A non-invasive method of determining glucose level according to Claim 1, wherein the weight for each calculated glucose level is based on the reliability of the calculated glucose level's respective non-invasive measurement of the corresponding parameter.

In claim 17, line 3, "with" was changed to --within--.

In claim 18, line 3, "with" was changed to --within--.

2. The following is an examiner's statement of reasons for allowance. U.S. Patent 6,070,093 to Oosta et al. (Oosta) teaches the steps of measuring distinct parameters

from the body for the calculation of glucose (Abstract of Oosta) but Oosta uses these measurements to calculate one glucose level (column 7, line 15 to column 9, line 51 of Oosta). Oosta does not teach the steps of calculating a different glucose level from each measured parameter as required in claims 1, 6, and 19 of the present application.

U.S. Patent Application Publication 2003/0130616 to Steil et al. (Steil) teaches the calculation of two distinct parameters from the body for the calculation of two distinct glucose levels. Steil further teaches that the two glucose levels are either combined to form a weighted average or one glucose level is used as a check on the other glucose level. (paragraph 0308 of Steil). Steil does not teach the use of three distinct parameters as required in claims 1, 6, and 19 of the present application. Also, Steil does not teach comparing the glucose levels for the determination of a weighted average as required in claims 1 and 6 of the present application. Finally, Steil does not teach the steps of calculating a weighted average and confirming the accuracy of the glucose calculation using one of the parameters as required in claim 19 of the present application.

U.S. Patent 6,882,940 to Potts et al. (Potts) teaches a method for determining a hypoglycemic even by measuring glucose values, body temperature, and skin conductance. (column 27, line 11 to column 28, line 4 of Potts). Potts does not teach the steps of calculating different glucose levels from different measured parameters as required in claims 1, 6, and 19 of the present application

Thus, the prior art does not teach or suggest the steps of non-invasively measuring three distinct parameters of the body from which glucose level can be

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calculated; calculating the corresponding glucose level for each of the three measurements; and calculate a weighted average from two or three calculated glucose levels.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kremer whose telephone number is 571-272-4727. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew Kremer
Assistant Examiner
Art Unit 3736



ERIC F. WINAKUR
PRIMARY EXAMINER